Supporting Statement For
Reprocessed Single-Use Device Labeling
(21 U.S.C. 352(u))
Docket # 2005N-0389
OMB Control Number 0910-0577

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

Section 502 (21 U.S.C. 352) of the Federal Food, Drug, and Cosmetic Act (the act), among other things, establishes requirements that the label or labeling of a medical device must meet so that it is not misbranded and subject to regulatory action. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250) amended section 502 of the act to add section 502(u) (21 U.S.C. 352(u)) (Attachment A) to require devices (both new and reprocessed) to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer. Section 2(c) of The Medical Device User Fee Stabilization Act of 2005 (MDUFSA) (Public Law 109-43) (Attachment B) amends section 502(u) (21 U.S.C. 352(u)) by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Under the amended provision, if the original SUD or an attachment to it prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol, in a prominent and conspicuous manner on the device or attachment to the device. If the original SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse may identify itself using a detachable label that is intended to be affixed to the patient record. MDUFSA was enacted on August 1, 2005, and becomes self-implementing on August 1, 2006. MDUFSA requires that not later than 180 days after enactment, the Secretary of Health and Human Services shall issue guidance to identify circumstances in which the name or symbol of the original SUD manufacturer is not prominent and conspicuous, as used in section 502(u) of the act.

Information concerning the identification of the name of a reprocessor of single-use devices is necessary so that users do not misattribute adverse events associated with a reprocessed device to the original manufacturer. When reporting adverse events involving the use of reprocessed single-use devices, health care providers may mistakenly believe that the reprocessed device is a new product from the original manufacturer of the device and not from the reprocessor. The information and records generated under this labeling requirement will be used so that physicians, hospital staff, and patients can

associate a particular device with a particular manufacturer. This is especially important in the event of a recall, warning, patient injury, or product malfunction.

2. **Purpose and Use of the Information**

The primary users of the device labeling information are the health professionals who use or prescribe the device. It is essential to require the specific identification of reprocessed SUDs to ensure that physicians, nurses, users, and hospital administrators know that a device they have used was reprocessed. The intent of the labeling requirement is to ensure that physicians, hospital staff, and patients can identify the reprocessor of a SUD when an adverse event or risk to health information should be attributed to the responsible manufacturer.

Section 519 of the act requires manufacturers to report patient injuries and product malfunctions to FDA, and device user facilities to report these adverse events to FDA or the manufacturer. FDA's post-marketing surveillance program cannot work as intended unless health care providers, original manufacturers, device reprocessors, and FDA can readily and accurately identify when a SUD has been reprocessed. The lack of specific labeling to identify reprocessed devices may lead to incomplete and inaccurate reporting of patient injuries and product malfunctions involving reprocessed SUDs, particularly in an instance where a reprocessed device bears only the name or mark of the original manufacturer. The lack of adequate labeling to identify a reprocessor undercuts the purpose and effectiveness of section 519 of the act and FDA's medical device reporting regulations such that FDA lacks accurate information of the post-market safety and effectiveness of reprocessed SUDs.

Failure of the reprocessor to label the SUD; either on the device itself, an attachment to the device, or with a detachable label; may result in the product being misbranded under the act subjecting the firm and the product to regulatory action. Any SUD reprocessed from an original device that the original manufacturer has prominently and conspicuously marked must be prominently and conspicuously remarked with the reprocessor's name, a generally recognized abbreviation of its name, or a unique and generally recognized symbol for it.

3. Use of Information Technology and Burden Reduction

Manufacturers, including reprocessors, of SUDs may use any appropriate information technology to develop and distribute the required labeling. In general, the statute requires paper copies for labeling accompanying a device. Under section 502(u) of the act, (21 U.S.C. 352(u)) manufacturers may use paper labeling or any technology such that the SUD itself or an attachment to the SUD bears prominently and conspicuously the name of manufacturer. Manufacturers may use appropriate information technology to keep records of labeling required by section 502(u) of the act.

4. Efforts to Identify Duplication and Use of Similar Information

The information required to be disclosed by this statutory labeling provision is available only from the manufacturer of a SUD and the reprocessor of a SUD and is not otherwise available to the user of the devices.

5. **Impact on Small Business or Other Small Entities**

The labeling information is required in order to comply with section 502(u) of the act. The information that is required to be disclosed is information that is available to the firm, including a small business, as a normal course of its doing business.

FDA aids small business and manufacturers to comply with applicable statutes and regulations by providing guidance and information through the Division of Small Manufacturers, International, and Consumers Assistance (DSMICA) and the Device Registration and Listing Branch within the Center for Devices and Radiological Health. DISMICA provides workshops, on-site evaluations and other technical and nonfinancial assistance to small manufacturers. The workshops make available publications and educational materials, which include medical device labeling information. The Division also maintains a toll-free 800 telephone number and a website which firms may use to obtain regulatory compliance information.

6. **Consequences of Collecting the Information Less Frequently**

The statutes and regulations generally require that labeling accompany each shipment of a device. If this were not done, the device user may not have the necessary information for the safe and effective use of the device.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.

This information collection is consistent with 5 CFR 1320.5.

8. **Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

FDA regularly consults with representatives of industry to discuss various regulatory issues including labeling issues in general and with regard to specific devices. The statutory labeling provisions and labeling regulations are generally very flexible and FDA is often able to work with industry to accommodate concerns without changing labeling requirements. FDA also regularly makes available guidance documents with device specific recommendations for conforming to labeling requirements. When FDA makes these guidance documents available, FDA provides an opportunity for interested person to comment. FDA revises the guidance documents as the comments warrant.

In response to industry requests, FDA issued on June 23, 2003, a draft guidance document "Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002 – Identification of Manufacturer of Medical Devices. (Attachment C) The draft guidance addressed the implementation of section 301 of MDUFMA, which amended section 502 of the act to require a device, or an attachment to the device, to bear prominently and conspicuously the name of the manufacturer. Failure to comply with the new requirement would misbrand the device under section 502(u) of the act (21 U.S.C. 352(u)). In the exercise of enforcement discretion, FDA stated that it would not object if a manufacturer has not fully implemented the changes required by section 301 of MDUFMA after April 26, 2004, the self-implementing effective date of the labeling provision. FDA chose to exercise its enforcement discretion with respect to section 502(u) of the act because there were significant concerns about the provision as it applied to all devices, and it included a potentially burdensome waiver provision.

The following are among those with whom FDA regularly consults on regulatory issues:

AdvaMed
1200 G Street, NW
Suite 400
Washington, DC 20005
(202) 783-8700
Contact: Janet Trunzo

Food and Drug Law Institute (FDLI)
1701 K Street, NW
Suite 904
Washington, DC 20006
(202) 371-1420
Contact: Jerome Halperin

Regulatory Affairs Professional Society (RAPS)
11300 Rockville Pike
Suite 1000
Rockville, MD 20852
(301) 770-2920
Contact: Ms. Linda Temple

National Electrical Manufacturers Association (NEMA)
1300 North 17th Street
Suite 1847
Rosslyn, VA 22209
(703) 841-3200
Contact: Mr. Robert Britain

Medical Device Manufacturers Association (MDMA)
1900 K Street, NW
Suite 300
Washington, DC 20006
(202) 496-7150
Contact: Stephen Northrup

The 60-Day notice has been published in the Federal Register on September 29, 2005 (70 FR 56910) soliciting comments on this information collection prior to its submission to the Office of management and Budget (OMB) as required by 5 CFR 1320.8(d). (Attachment D)

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided by Respondent

Information that is made available in labeling is, by its nature, public information. Information that is trade secret or confidential is subject to FDA's regulations on the release of information, 21 CFR Part 20.

11. Justification for Sensitive Questions

This information collection does not involve any questions of a sensitive nature.

12. Estimate of Hour Burden Including Annualized Hourly Costs

FDA estimates the burden of this collection of information as follows:

Table 1. --- Estimated Annual Reporting Burden *

21 U.S.C. §	No. of Respondents	Annual Responses Per Respondent	Total Annual Responses	Hours per Response	Total Hours
352(u)	3	100	300	0.1	30

*There are no capital costs or operating and maintenance costs associated with this information collection.

The requirements of §352(u) impose a minimal burden. This section only requires the manufacturer, packer, or distributor of a device to include their name and address on the labeling of a device. This information is readily available to the establishment and easily supplied. From its registration and premarket

submission database, FDA estimates that there are 3 establishments that distribute approximately 300 reprocessed SUDs. Each response is anticipated to take 0.1 hours resulting in a total burden to industry of 30 hours.

Multiplying the total reporting and recordkeeping hours (30) by an average rate of $67.71 per hour (mean hourly rate for management occupations plus fringe benefits) yields an estimated annual cost to respondents of $2,031.

13. Estimate of the Other Total Annual Cost Burden to Respondent or Recordkeepers

No capital, operating, or maintenance costs are associated with this information collection. Establishments would label their devices in some form as part of their usual and customary business practices.

14. Annualized Cost to the Federal Government

Generally, FDA would review compliance with the new labeling requirement under section 502(u) of the act as part of a postmarket program. FDA estimates from its time reporting system that labeling reviews currently expend approximately 10 FTEs. Review of the new labeling provision under section 502(u) of the act would expend 0.5 FTE. Based on an average person-year cost of $180,000 and including an allowance for overhead, FDA estimates that this amount of time is equivalent to a cost to the Federal government of approximately $90,000.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collection associated with the labeling requirement for SUDs is based the self-implementing effective date of August 1, 2006, which is established by operation of Section 2(c) of MDUFSA.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Not applicable.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

FDA has not identified any exceptions to the certification statement identified in Item 19 of the Instructions for completing OMB Form 83-I.

B. Collection of Information Using Statistical Methods

There are no plans to publish the information collected under the provision of this statutory requirement for statistical use. The collections of information for which FDA is seeking approval do not employ statistical methods.

LIST OF ATTACHMENTS

Attachment A -	21 U.S.C. 352
Attachment B -	Medical Device User Fee Stabilization Act of 2005
Attachment C -	Draft Guidance for Industry and FDA Staff, "Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002 – Identification of Manufacturer of Medical Devices"
Attachment D-	60-day Federal Register notice